REMARKS

Claims 1-27 and 48-53 are currently pending. Independent claims 1 and 27 have been amended to further define the particular boundaries of the pocket. In particular, claim 1 has been amended to recite that the pocket is defined by the area of direct bonding together of the first liner and the second liner, and claim 27 has been amended to recite that the pocket is defined by the area of direct joining together of the first liner and the second liner. Support for these amendments may be found, for example, at paragraphs [0033] and [0074] and Figures 2-5 of the application as filed. New claims 52 and 53 have been added, which recite that the pocket has been pre-treated with a supplementary material to aid in incorporating said bioactive agent into said pocket. New claims 54 and 55 have been added, which recite that the first liner and second liner are directly bonded to each other at a location at a location coextensive with or within an inner surface of the said structural member. Support for this amendment can be seen in Figures 2-5 of the application as filed. In view of these amendments and the corresponding remarks below, reconsideration of the rejections of the Office Action is respectfully requested.

Claim Rejection Under 35 U.S.C. §102(b)

The Examiner has rejected claims 1-10, 13-15, 27, 48 and 50 under 35 U.S.C. 102(b) as allegedly anticipated by Houser et al. (U.S. Patent No. 6,149,681). The Examiner has stated that Houser discloses the composite device having a first polymeric layer, a second polymeric layer, and an intermediate structural member therebetween. The Examiner further alleged that Houser disclosed the first liner bonded to the second liner through the openings to form a pocket, the pocket containing a fluid containing a bioactive agent.

The Applicant has amended the claims of the application. In particular, independent claim 1 has been amended to recite that the pocket is defined by "the area of direct bonding together of said first liner and said second liner." Similarly, independent claim 27 has been amended to recite that the pocket is defined by "the area of direct joining together of said first

liner and said second liner." The Applicant respectfully submits that Houser does not disclose the particular limitation as presently claimed.

Houser generally discloses the use of two liners with an intermediate support member, and discloses that a pocket containing a bioactive agent may be formed. However, Houser does not disclose that the pocket is defined by the first liner, the second liner, the support member, and the area where the first liner and second liner are bonded or joined together. Rather, Houser states that one layer of graft material can be joined to the structural layer, and then "a second layer of the graft material is secured to the structural layer." (Col. 3, lines 41-45) (emphasis added). The pair of graft layers can then be used to provide a pocket for containing a drug solution. (Col. 3, lines 45-48). Thus, the drug-containing pocket of Houser is actually defined by the first layer, the second layer, and two surfaces of the support member.

In each and every instance that the drug-containing pocket is described in Houser, it is formed by the two graft layers supported by the intermediate support member, and not bonded to each other. Houser does not disclose or intend that the pocket could be defined by the first layer, the second layer, the support structure, and the area where the first and second layers are bonded to each other.

Houser's drug-containing pocket is only defined by the first layer, the second layer, and two sides of the support member. This is evident throughout the specification and figures, and in particular, Figure 16, which is specifically described as "a sectional view showing a portion of a graft with two layers of graft material to form a pocket." Houser defines the formation of the pocket as "a graft 150 in which two graft material layers, indicated at 152 and 154, are provided on opposite sides of a structural layer 156. This construction forms a pocket 158 between spaced apart sections 160 and 162 of the structural layer." (Col. 10, lines 46-50) (emphasis added). Houser then explains that a drug solution may be disposed within the

pocket. Houser sets forth no other formation of the drug-containing pocket. Figure 16 is shown below:

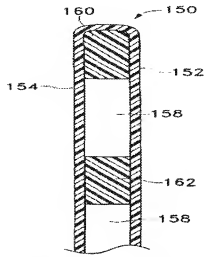


FIG. 16

While Houser does describe a drug-containing pocket, Houser requires that the pocket (158) be formed between the spaced sections of the support member (160 and 162). In fact, the claims set forth in Houser specifically state that the second graft layer is "supported by the structural layer". (Col. 15, lines 24-25; Col. 17, lines 9-10; Col. 18, lines 8-9 and 45-46). No other pocket formation is disclosed in Houser. Although Houser generally states that two graft layers may be bonded together about a support strand (Col. 13, lines 15-16), this disclosure is not in conjunction with the formation of a drug-containing pocket. Houser does not disclose or even suggest that this formation may form the drug-containing pocket. As set forth above, the only disclosure of a drug-containing pocket is where the pocket is formed by the layers and two sides of the support member.

In contrast, the claims as currently pending require that the bioactive agent-containing pocket be defined by the area of direct bonding or joining together of the first liner and the second liner. This formation is not disclosed, either explicitly or inherently in Houser. As

such, it is respectfully submitted that claims 1-10, 13-15, 27, 48 and 50 are patentable over Houser. Withdrawal of this rejection is respectfully requested.

New claims 52 and 53 have been added, which are dependent on claims 1 and 27, respectively. Although they are deemed patentable over Houser as explained above, they are further patentable over Houser, since Houser does not disclose using a pre-treated pocket, where the pocket has been treated with a supplementary material to aid in incorporating said bioactive agent into said pocket. In addition, new claims 54 and 55 have been added, which are dependent on claims 1 and 27, respectively, and are further patentable over Houser since Houser does not disclose bonding or joining the two layers at a location coextensive with or within an inner surface of the said structural member. It is likewise submitted that these new claims are likewise patentable over Houser for the reasons set forth above.

Claim Rejection Under 35 U.S.C. §103(a)

The Examiner has rejected claim 11 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Rudakov et al. (U.S. Patent No. 6,451,050). The Examiner relied upon Rudakov for disclosing the bioactive agent encapsulated in a polymeric matrix.

As explained above, Houser fails to disclose the drug-containing pocket as set forth in claim 1. Rudakov fails to remedy this deficiency, and in fact. Rudakov specifically sets forth a pocket that is defined by the first and second liners and supporting members (17). Rudakov does not disclose the pocket formation as specifically claimed. As such, dependent claim 11 is patentable over Houser and Rudakov, whether taken alone or in combination. Withdrawal of this rejection is respectfully submitted.

The Examiner then rejected claim 12 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Rudakov and further in view of Helmus (U.S. Publication No. 2002/0032477). The Examiner relied upon Helmus for the disclosure of a biological prosthesis

that uses microparticles in a matrix. As explained above, Houser and Rudakov fail to disclose the drug-containing pocket as set forth in claim 1, either separately or in combination. Helmus fails to remedy this deficiency. As such, dependent claim 12 is patentable over Houser, Rudakov, and Helmus whether taken alone or in combination. Withdrawal of this rejection is respectfully submitted.

The Examiner also rejected claims 16 and 21-26 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Golds et al. (U.S. Patent No. 6,001,125). The Examiner relied upon Golds for disclosing a vascular graft constructed from porous ePTFE. As explained above, Houser fails to disclose the drug-containing pocket as set forth in claim 1. Golds fails to remedy this deficiency. As such, dependent claims 16 and 21-26 are patentable over Houser and Golds, taken alone or in combination. Withdrawal of this rejection is respectfully requested.

The Examiner then rejected claim 17 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Buirge et al. (U.S. Patent No. 5,693,085). The Examiner relied upon Buirge for the disclosure of using a biological prosthesis that uses a natural polymer. As explained above, Houser fails to disclose the drug-containing pocket as set forth in claim 1. Buirge fails to remedy this deficiency. As such, dependent claim 17 is patentable over Houser and Buirge, taken alone or in combination. Withdrawal of this rejection is respectfully requested.

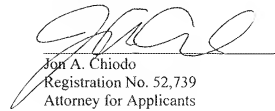
The Examiner also rejected claim 18 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Yan (U.S. Patent No. 6,240,616). The Examiner relied upon Yan for the disclosure of using a bioabsorbable polymer. As explained above, Houser fails to disclose the drug-containing pocket as set forth in claim 1. Yan fails to remedy this deficiency. As such, dependent claim 18 is patentable over Houser and Yan, taken alone or in combination. Withdrawal of this rejection is respectfully requested.

The Examiner also rejected claims 19-20 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Rhodes (U.S. Patent No. 5,665,117). The Examiner relied upon Rhodes for the disclosure of using stainless steel or tantalum to construct the support member. As explained above, Houser fails to disclose the drug-containing pocket as set forth in claim 1. Rhodes fails to remedy this deficiency. As such, claims 19-20 are patentable over Houser and Rhodes, taken alone or in combination. Withdrawal of this rejection is respectfully requested.

The Examiner finally rejected claims 49 and 51 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Yang et al. (U.S. Publication No. 2002/0062147). The Examiner relied upon Yang for the disclosure of using a gel to contain the bioactive agent. As explained above, Houser fails to disclose the drug-containing pocket as set forth in claims 1 and 27. Yang fails to remedy this deficiency. Claims 49 and 51 are patentable over Houser and Yang, taken alone or in combination. Withdrawal of this rejection is respectfully requested.

Applicant has responded in full to the present Office Action. It is believed that all of the claims of the present invention are patentable over the cited references, either alone or in combination. Favorable action thereon is respectfully solicited. Should the Examiner have any questions or comments concerning this Response, the Examiner is respectfully invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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